K090923

PARCUS Medical, LLC

SURGICAL INNOVATION >> VALUE DRIVEN

JUN 30 2009

510(k) Summary

Submitter: Parcus Medical, LLC
839 South Neenah Ave.
Sturgeon Bay, WI 54234

Company Contact: Barton Bracy
Phone: (920) 746-2972
Fax: (920) 746-8665

Date Prepared: March 30, 2009

Trade Name: Parcus GFS

Common Name: Suture Retention Device

Classification Name: Fastener, Fixation, Non-Degradable, Soft Tissue
21 CFR 888.3040 – Product Code HWC and MBI

Predicate Devices:

- Smith & Nephew EndoButton (K980155, K081098)
- ConMed Linvatec XO Button (K070780)

Device Description:

The Parcus GFS is a titanium implant assembled with #5 suture threaded through four holes. The loops created by this process vary in length from 10mm-30mm and are used to suspend the graft. The titanium portion of the assembly is supplied in sizes, Standard and Large, to accommodate tunnels of different diameters.

Intended Use:

The Parcus GFS is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

Substantial Equivalence Summary:

The Parcus GFS is substantially equivalent to the predicate device listed above in which the basic features and intended uses are the same. Any differences between the GFS and the predicate device are considered minor and do not raise questions concerning safety and effectiveness.

Summary Performance Data:

The pull out strength was measured for both the Standard and Large GFS. Side by side comparisons were done with the predicate devices and results of the pull-out testing demonstrated that the Parcus GFS is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

Parcus Medical, LLC
% Mr. Barton Bracy
VP Marketing and Product Development
839 South Neenah Avenue
Sturgeon Bay, Wisconsin 54234

Re: K090923
Trade/Device Name: Parcus GFS
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: MBI, GAT
Dated: March 30, 2009
Received: April 1, 2009

Dear Mr. Bracy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090923

Device Name: Parcus GFS

Indications for Use:

The Parcus GFS is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

Prescription Use __X__ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090923